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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,928	07/21/2003	Ulrich Posanski	4-20017F	6463

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,928	POSANSKI, ULRICH	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination filed under 37 CFR 1.114 and remarks filed 10/29/07. Claims 11-20 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The examiner does not find support for the new requirement that the composition be "devoid of hydrophilic phase" in the original specification as is now recited in claims 11 and 17.

Applicant has not provided the section or paragraph of the specification that provides support for absence or presence of hydrophilic phase. The specification at paragraph [0048] of the published specification mentions "colloidally dispersed phase."

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 17 requires the carrier composition to be "devoid of hydrophilic phase" while the nonionic amphiphilic surfactant has polyethylene oxide as the hydrophilic component. Since the surfactant is part of the carrier, it is not clear how the surfactant which has hydrophilic component does not contribute hydrophilic phase.

Response to Arguments

6. Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive.

7. Applicant argues that the skilled artisan at the time the invention was made recognizes/understands non-ionic amphiphilic substance/surfactant to have hydrophobic and hydrophilic regions that does not necessarily contribute to a hydrophilic phase within a pharmaceutical composition and would not certainly contribute to any hydrophilic phase in a carrier composition, but applicant has not shown with the documents presented to support the

argument or by the argument that the hydrophobic and the hydrophilic regions of the surfactant are in 50:50. Furthermore, while the examiner agrees with applicant that an *amphiphilic* or amphipathic compound is a chemical compound possessing both hydrophilic and hydrophobic properties, an amphiphilic compound is not always 50% hydrophobic or 50% hydrophilic. Therefore, depending on how much of the surfactant is hydrophilic, a 50% of the surfactant may contribute to the hydrophilicity of the carrier. It is thus unclear how the carrier is devoid of hydrophilic phase.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-19 are rejected under 35 U.S.C. 102(b) as anticipated by Polanski (GB 2 228 198 A).

Polanski discloses pharmaceutical composition that contains cyclosporine meeting the limitations of the active agent in claims 11, 13 and 17; carrier composition that contains oils, tenside having HLB of 10 and cremophor (Examples 1 and 2; pages 11-13, page 16), meeting the carrier limitation often the claims. On page 10, line 4, Polanski describes the composition as not being aqueous meeting the requirement to exclude hydrophilic phase. The amounts in the examples meet the amounts in the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polanski (GB 2 228 198 A).

12. Polanski is described above. The formulation of Polanski is an oral formulation (title, abstract). Polanski does not specifically teach tablets or capsules as recited in claim 20. However, tablet and capsule are oral dosage forms. Therefore, taking the broad oral teaching of Polanski, the person one having ordinary skill in the art would have reasonable expectation of success in formulating the dosage form of Polanski in tablet or oral dosage form for oral administration.

13. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavanak (US 5,639,724).

Cavanak discloses composition containing cyclosporin as the active agent, glycerol fatty acid ester and tenside having HLB of 10 (abstract) meeting the requirements of claims 11-18. Cavanak describes a variety of cyclosporin compositions that contains sesame oil, TWEEN or CREMOPHOR , triglyceride, neutral oils (column 5, lines 12-20), tri- and di-glycerides, CREMOPHOR (column 8, lines 12-18), sorbitan monolaurate (column 14, lines 43-67) and the process of combining the components into the formulation meets process claim 20. See also column 13, lines 45-67; column 14, lines 6-43. Cavanak does not describe the presence of

hydrophilic phase. Cavanak contemplates oral dosages of granules, tablets, capsules and drink solutions (Column 21, lines 15 and 16) meeting claim 20

Cavanak does not however teach the percent amounts of the carrier components. However, Cavanak teaches the general conditions of the composition and differs by not teaching the respective amounts. But in general, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, taking the teachings of Cavanak, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success to formulate the dosage form of Cavanak using amounts of the components that when combined would be effective in achieving the desired dosage form.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 27-35 and 37, 1-10, 1-10 of copending Application Nos. 11/453504, 10/961785 and 10/623887 respectively. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated, or would have been obvious, over the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In the present case, claims 11 and 13 of the examine application reads on at least claims 1 and 3 of co-pending applications 10/961,785 and 10/623,887 and claims 1, 27, 29, 31-33 and 37 of co-pending 11/453,504.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
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